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UNITED STATES

DISTRICT COURT

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

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LOUISIANA WHOLESALE DRUG)
COMPANY, INC., on behalf of)
itself and all others)
similarly situated,)
)
Plaintiff,)
v.)
)
PFIZER INC., and)
WARNER-LAMBERT CO.,)
)
Defendants.)
-----)

Civ. No. 02-1830 (JCL)

CLASS ACTION COMPLAINT

Plaintiff, Louisiana Wholesale Drug Company, Inc., 2085 I-49 South Service Road, Sunset, Louisiana 70584, on behalf of itself and all others similarly situated, for its Class Action Complaint ("Complaint") against defendants Pfizer Inc., 235 East 42nd Street, New York, New York, and Warner-Lambert Co., 201 Tabor Road, Morris Plains, New Jersey (collectively "Defendant" or "Pfizer") alleges as follows based on: (a) personal knowledge; (b) the investigation of its counsel, including review of various pleadings and court orders in patent infringement litigations pending in the United States District Courts for the Northern

District of Illinois and the District of New Jersey, discussed herein; and (c) information and belief:

I. NATURE OF THE ACTION

1. This is a civil antitrust action seeking treble damages and other relief arising out of Pfizer's unlawful exclusion of competition from the market for gabapentin anhydrous, an anti-convulsant drug manufactured by Pfizer under the brand-name Neurontin. As alleged below, Pfizer used various illegal and deceptive means to improperly create patent protection for Neurontin, and to abuse the monopoly power created thereby. Pfizer accomplished the scheme by wrongfully listing certain patents in the Food & Drug Administration ("FDA") publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), and by wrongfully conducting baseless litigation to both protect those fraudulently listed patents against challenges by generic manufacturers, and to trigger an automatic 30-month regulatory stay.

2. According to Pfizer's Annual Report, during the twelve months ending December 31, 2000, Pfizer's sales of Neurontin exceeded \$1.3 billion. No competing generic version of Neurontin is currently marketed in the United States.

3. As a result of Pfizer's illegal acts, Pfizer has (1) illegally maintained its monopoly in the market for gabapentin anhydrous (Neurontin and generic versions of

Neurontin); (2) fixed, raised, maintained, and/or stabilized the price of Neurontin at supra-competitive levels; and
(3) overcharged Plaintiff and other direct purchasers of Neurontin millions of dollars by depriving them of the benefits of competition from cheaper generic versions of Neurontin.

4. Pfizer possesses unlawful monopoly power in the market for gabapentin anhydrous in the United States, which it willfully acquired and maintains, as distinguished from growth or development as a consequence of a superior product, business acumen or historic accident.

II. JURISDICTION AND VENUE

5. This Complaint is filed and these proceedings are instituted under Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15 and 26, to recover treble damages and the costs of suit, including a reasonable attorneys' fee, for the injuries sustained by Plaintiff and members of the Class resulting from violations by the Defendant, as hereinafter alleged, of Section 2 of the Sherman Act, 15 U.S.C. § 2. The jurisdiction of this Court is based upon 28 U.S.C. §§ 1331 and 1337(a) and 15 U.S.C. § 15.

6. The Defendant named herein is found or transacts business within this judicial district, and the interstate trade and commerce, hereinafter described, is carried out, in substantial part, in this district. Venue, therefore, is

appropriate within this district under 15 U.S.C. § 22 and 28 U.S.C. § 1391(b) and (c).

III. THE PARTIES

7. Plaintiff Louisiana Wholesale Drug Company, Inc. ("Plaintiff" or "Louisiana Wholesale") is a corporation organized under the laws of the State of Louisiana and is located at 2085 I-49 South Service Road, Sunset, Louisiana 70584. Plaintiff purchased the prescription drug gabapentin anhydrous (sold under the brand-name "Neurontin") directly from Pfizer during the Class Period as defined below.

8. Defendant Pfizer Inc. is a Delaware corporation with its principal place of business at 235 East 42nd Street, New York, New York. Pfizer is in the business, among other things, of developing, manufacturing, distributing, advertising, and selling Neurontin throughout the United States through its subsidiary Warner-Lambert.

9. Defendant Warner-Lambert is a wholly-owned subsidiary of Pfizer, and is located at 201 Tabor Road, Morris Plains, New Jersey, in this federal judicial district. Warner-Lambert is in the business, among other things, of developing, manufacturing, distributing, advertising, and selling Neurontin throughout the United States. Warner-Lambert was an independent public company until June 2000, when it was acquired by Pfizer. Prior to the acquisition, Neurontin was marketed by Warner-Lambert.

IV. CLASS ACTION ALLEGATIONS

10. Plaintiff brings this action on behalf of itself and, under Rule 23 of the Federal Rules of Civil Procedure, as representative of a Class defined as follows:

All persons who directly purchased Neurontin from Pfizer at any time during the period of January 16, 2000 through the present (the "Class Period").

Excluded from the Class are Defendant and its officers, directors, management and employees, subsidiaries or affiliates.

11. Members of the Class are so numerous that joinder is impracticable. While the exact number of Class members is unknown to Plaintiff, it is believed to be at least in the hundreds. Furthermore, the Class is readily identifiable from information and records in the possession of Defendant Pfizer.

12. Plaintiff's claims are typical of the members of the Class. Plaintiff and all members of the Class were damaged by the same wrongful conduct by the Defendant, i.e., they have paid artificially inflated prices for gabapentin anhydrous and were deprived of the benefits of competition from cheaper generic versions of Neurontin as a result of Defendant's wrongful conduct.

13. Plaintiff will fairly and adequately protect and represent the interests of the Class. Plaintiff's interests are coincident with, and not antagonistic to, those of the Class.

14. Plaintiff is represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation, particularly class action antitrust litigation in the pharmaceutical industry.

15. Questions of law and fact common to the members of the Class predominate over questions, if any, that may affect only individual Class members because Defendant has acted on grounds generally applicable to the entire Class. Such generally applicable conduct is inherent in Defendant's wrongful conduct.

16. Questions of law and fact common to the Class include:

- a. whether the conduct alleged herein constitutes a violation of the antitrust laws;
- b. the definition of the relevant market for analyzing Defendant's monopoly power;
- c. whether Defendant had monopoly power in the relevant market;
- d. whether Defendant's actions illegally maintained Defendant's monopoly power in the relevant market;
- e. whether the activities of Defendant as alleged herein have substantially affected interstate commerce; and
- f. whether, and to what extent, Defendant's conduct caused antitrust injury to the business or property of its direct purchaser customers and if so, the appropriate measure of damages.

17. Class action treatment is a superior method for the fair and efficient adjudication of the controversy, in that, among other things, such treatment will permit a large number of similarly situated persons to prosecute their common claims in a

single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress on claims that it might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

18. Plaintiff knows of no difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

V. FACTUAL BACKGROUND

A. The Regulatory Structure Pursuant to Which Generic Substitutes for Brand-Name Drugs Are Approved

19. Under the Federal Food, Drug, and Cosmetics Act (21 U.S.C. §§ 301-392) manufacturers who create a new, pioneer drug must obtain the approval of the Food and Drug Administration ("FDA") to sell the new drug by filing a New Drug Application ("NDA"). An NDA must include submission of specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents.

20. In 1984, Congress amended the Food, Drug and Cosmetics Act with the enactment of the Hatch-Waxman amendments, called the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) ("Hatch-Waxman").

21. Hatch-Waxman simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file a lengthy and costly NDA in order to obtain FDA approval. Instead, the FDA provides an expedited review process by which generic manufacturers may file an Abbreviated New Drug Application ("ANDA").

22. The ANDA relies on the scientific findings of safety and effectiveness included by the brand-name drug manufacturer in the original NDA. The ANDA filer must show the FDA that the generic drug it is going to market is chemically equivalent to the brand-name drug.

23. As a counter-balance, Hatch-Waxman streamlined the process for a brand-name manufacturer to enforce its patents against infringement by generic manufacturers, and provided the brand-name manufacturer with what is essentially a preliminary injunction, in the form of a 30-month stay.

24. When the FDA approves a brand-name manufacturer's NDA, the FDA publishes any patents which, according to information supplied to the FDA by the brand-name manufacturer, claim the approved drug or its approved uses, in a publication entitled the "Approved Drug Products with Therapeutic Equivalence Evaluations," known as the "Orange Book." 21 U.S.C. §355(j)(7)(A)(iii). The FDA does not check the facts supplied to it by the brand-name manufacturer, but trusts that the

manufacturer will be truthful. After the NDA is approved, the brand-name manufacturer may list other new patents in the Orange Book as related to the NDA, if the brand-name manufacturer similarly certifies that the new patents claim either the approved drug or its approved uses.

25. To obtain FDA approval of an ANDA (and thus the right to sell a generic version of a brand-name drug), a generic manufacturer must certify that the generic drug addressed in its ANDA does not violate any patent listed in the Orange Book as claiming the brand-name drug.

26. Under Hatch-Waxman, a generic manufacturer's ANDA must contain one of four certifications:

- a. that no patent for the brand-name drug has been filed with the FDA;
- b. that the patent for the brand-name drug has expired;
- c. that the patent for the brand-name drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "paragraph III certification"); or
- d. that the patent for the brand-name drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "paragraph IV certification").

21 U.S.C. §355(j)(2)(A)(vii).

27. If a generic manufacturer files only a paragraph III certification, then it is able to take advantage of the expedited Hatch-Waxman approval process, and the FDA must act on the

application within 180 days of receipt, unless both the FDA and the applicant agree to extend the deadline. 21 U.S.C. §355(j)(5)(A). If the FDA approves the ANDA, the approval can become effective on the date certified as the patent expiration date. 21 U.S.C. §355(j)(5)(B)(ii).

28. If a generic manufacturer files a paragraph IV certification, that the patent is invalid or will not be infringed, then the brand-name manufacturer has the opportunity to slow the process down. This is because a generic manufacturer filing a paragraph IV certification must promptly give notice of this fact to both the NDA owner and the owner of the patent(s) at issue. The generic manufacturer's act of filing a paragraph IV certification triggers the time by which a patent owner may file an action for patent infringement, and take advantage of a stay of FDA approval of the generic version of the NDA owner's drug.

29. If the patent owner fails to initiate a patent infringement action within 45 days after receiving the generic manufacturer's paragraph IV certification, then the FDA may finally approve the generic manufacturer's ANDA upon satisfying itself as to the equivalency of the generic to the brand-name drug. If, however, the patent owner initiates an infringement action against the ANDA filer within 45 days, then the FDA may not finally approve the ANDA until the earlier of either 30 months or the issuance of a decision by a court that the patent

is invalid or not infringed by the generic manufacturer's ANDA.
21 U.S.C. §355(j)(5)(B)(iii).

30. Typically, generic versions of brand-name drugs are initially priced significantly below the brand-name versions. As a result, direct purchasers substitute generic versions of the drug for some or all of their purchases. As more generic manufacturers enter the market, prices for generic versions of a drug predictably decrease even further because of competition among the generic manufacturers, and the brand-name drug continues to lose even more market share. This price competition benefits all direct purchasers of the drugs who are able to: (a) purchase generic versions of a drug at substantially lower prices and/or (b) purchase the brand-name drug at a reduced price. However, until a generic manufacturer enters the market, the brand-name manufacturer has no competition, and therefore, little incentive to offer lower prices.

31. Consequently, brand-name drug manufacturers have an interest in delaying the process by which generic competition is introduced. Therefore, if a brand-name drug manufacturer can cause the FDA to list other related unexpired patents in the Orange Book, the generic manufacturers will have to file paragraph IV certifications as to these newly-listed patents. These certifications, in turn, will allow the brand-name drug manufacturer to sue the prospective generic manufacturer for

patent infringement, and trigger the Hatch-Waxman 30-month stay described above.

B. Neurontin

32. Neurontin is the brand name for the anti-convulsant, gabapentin anhydrous. Gabapentin anhydrous is approved by the FDA for only one use, the treatment of epilepsy. The gabapentin in Neurontin is "anhydrous", because no water is associated with the gabapentin molecules. Neurontin is manufactured and marketed in 100, 300, and 400 mg. capsules, and in 600 and 800 mg. tablets.

33. In 1993, Warner-Lambert obtained FDA approval to market its Neurontin brand gabapentin anhydrous for the treatment of epilepsy, and Warner-Lambert (now part of Pfizer) has sold Neurontin free from generic competition ever since. As of the filing of this complaint, no generic gabapentin anhydrous is sold in the United States.

34. Neurontin was protected by two patents; U.S. Patent No. 4,024,175 ("the '175 patent"), which claimed the chemical gabapentin anhydrous, and U.S. Patent No. 4,087,544 ("the '544 patent") which claimed the use of gabapentin anhydrous for "adjunctive therapy in the treatment of partial seizures with and without secondary generalization in adults with epilepsy". The '175 patent was issued in 1977 and expired in 1998. The '544 patent was issued in 1979 and expired on January 16, 2000. Therefore, as of January 16, 2000, no issues of patent

infringement prevented any generic manufacturer from selling gabapentin anhydrous for the treatment of epilepsy.

35. Faced with the loss of substantial revenues once the '544 patent expired, Pfizer devised a scheme whereby it could take advantage of the 30-month stay provided for by Hatch-Waxman, and thus extend the life of its Neurontin monopoly for several more years. To accomplish this, Pfizer needed to first list additional unexpired patents in the Orange Book as claiming Neurontin.

36. In addition to the two aforementioned patents, Pfizer owns three other gabapentin-related patents: U.S. Patent No. 4,894,476 ("the '476 patent"), which covers gabapentin monohydrate - i.e. gabapentin associated with one molecule of water - and which expires in 2008; U.S. Patent No. 5,084,479 ("the '479 patent"), which covers the use of gabapentin anhydrous for the treatment of neuro-degenerative diseases and expires in 2010, and U.S. Patent No. 6,054,482 ("the '482 patent"), which was issued to a German subsidiary of Pfizer, Godecke Aktiengesellschaft, and claims gabapentin anhydrous containing lactam and mineral acid. The '482 patent expires in 2017.

37. The FDA has not approved the use of gabapentin monohydrate, claimed by the '476 patent, for the treatment of any diseases. Therefore, the '476 patent should not have been listed in the Orange Book. If Pfizer wanted to petition the FDA to

approve gabapentin monohydrate, as indicated for a particular therapeutic use, it would have to file a new NDA. If and when the FDA approved Pfizer's NDA, Pfizer could then legally list the '476 patent in the Orange Book.

38. The FDA has not approved the use of gabapentin anhydrous for the treatment of neuro-degenerative disorders, as claimed by the '479 patent, and therefore, the '479 patent should not be listed in the Orange Book. If Pfizer wanted to petition the FDA to approve gabapentin anhydrous for that use, it would have to file a new NDA. If and when the FDA approved Pfizer's NDA, Pfizer could then legally list the '479 patent -- for the use of gabapentin anhydrous in the treatment of neuro-degenerative disorders -- in the Orange Book.

39. The FDA has not approved the use of a gabapentin formula which is low in lactam impurities, claimed by the '482 patent, for the treatment of any diseases. Therefore, the '482 patent should not have been listed in the Orange Book. If Pfizer wanted to petition the FDA to approve a gabapentin formula which is low in lactam impurities, as indicated for a particular therapeutic use, it would have to file a new NDA. If and when the FDA approved Pfizer's NDA, Pfizer could then legally list the '482 patent in the Orange Book.

40. Despite the fact that these three patents were neither for the chemical compound sold as Neurontin, nor for the use

approved by the FDA as indicated for Neurontin, Pfizer caused the FDA to list the three new patents as covering Neurontin in the Orange Book. As alleged above, since Pfizer was successful in obtaining such listings, generic competitors were forced to amend their ANDAs and file paragraph IV certifications as to the newly-listed patents, thus allowing Pfizer to sue them for patent infringement and trigger the 30-month stay.

C. **Pfizer Deceives the FDA, In Order to List
The '476, '479, and '482 Patents In The Orange Book**

1. **The Requirements For Listing Patents In The Orange Book**

41. Not every patent obtained by a brand-name manufacturer is entitled to be listed in the Orange Book. The FDA will only list a patent in the Orange Book if: (a) the patent claims a drug or a method of using a drug for which the brand-name manufacturer has obtained FDA approval; and (b) a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use or sale of the approved drug. If patents do not meet both of these requirements, the FDA will not list them in the Orange Book.

42. As alleged herein, neither the '476 patent, nor the '479 patent, nor the '482 patent satisfies the first requirement, therefore, Pfizer had to deceive the FDA in order to get them listed.

2. The FDA's Limited, Ministerial Role in Listing Patents In The Orange Book

43. The FDA's role in determining which patents can be listed in the Orange Book is ministerial. The FDA is charged only with determining whether the above statutory listing requirements are met. The FDA does not, however, research whether or not a patent actually does claim the approved drug or method of using the drug, i.e. determine whether an applicant is misrepresenting the facts; nor does the FDA make a legal assessment as to the reasonableness or viability of a claim of infringement that the brand-name claims it could assert against a prospective generic manufacturer. Rather, the FDA simply ensures that the brand-name manufacturer submits the appropriate documentation representing that the statutory requirements are satisfied.

44. Thus, when Pfizer certified to the FDA that the statutory listing requirements were met, the FDA listed the '476, '479, and '482 patents in the Orange Book in reliance on Pfizer's certification, without substantively evaluating its merits.

45. But for Pfizer's misrepresentations to the FDA in connection with the listing of the '476, '479, and '482 patents, the FDA would not have listed them in the Orange Book. If those patents had not been listed in the Orange Book, then generic competitors would only have had to make paragraph III certifications when filing their ANDAs, relating to the

expiration of the '544 patent. Those paragraph III certifications would have enabled the FDA to approve the ANDAs on an expedited track -- within 180 days -- and they could have become effective on the date of the expiration of the '544 patent, January 16, 2000. Thus, from that date, generic competitors should have been able to market their generic gabapentin anhydrous in competition with Neurontin.

46. Because the '476, '479, and '482 patents did not claim either the chemical gabapentin anhydrous, or an FDA approved use of Neurontin, Pfizer's representations in its Orange Book listing application that those patents did claim Neurontin were false and misleading. Pfizer's acts in procuring the listing of the '476, '479 and '482 patents in the Orange Book were made in bad faith in an attempt to interfere with the entry of generic competitors into the relevant market. Pfizer had no reasonable basis for the representations it made to the FDA in order to obtain the listing of the '476, '479, and '482 patents in the Orange Book.

47. Pfizer's conduct in procuring the illegal listing of the '476, '479, and '482 patents in the Orange Book is not entitled to immunity under the Noerr-Pennington doctrine for the following reasons:

(a) The FDA's conduct in listing the '476, '479, and '482 patents was a purely ministerial act, and thus Pfizer's conduct

before the FDA does not constitute legally protected petitioning activity; and

(b) The Noerr-Pennington doctrine does not immunize or protect the act of deceiving the FDA.

D. Pfizer Files Multiple Infringement Suits Solely for the Purpose of Delay, Knowing That It Cannot Possibly Win Them

1. Purepac

48. On or about March 30, 1998, Purepac Pharmaceutical Co., a wholly-owned subsidiary of Faulding Inc. (referred to jointly herein as "Purepac"), filed ANDA No. 75-350 seeking approval of a generic version of gabapentin anhydrous 100, 300 and 400 mg. capsules. Purepac sought approval for the manufacture of the compound covered by the '175 patent, which had already expired in 1997, and for the use -- "adjunctive therapy in the treatment of partial seizures with and without secondary generalization in adults with epilepsy" -- covered by the '544 patent, which would expire less than two years hence, on January 16, 2000.

49. Purepac made a paragraph III certification as to the '544 patent, i.e. that the patent would expire on a particular date and the generic manufacturer did not seek to market it before that date. Purepac made a paragraph IV certification, i.e. that the patent was invalid or would not be infringed, as to the '476 patent, claiming gabapentin monohydrate. As to the '479 patent, for the use of gabapentin anhydrous in the treatment of

neuro-degenerative disorders, Purepac filed a statement claiming that the patent was inapplicable.

50. On or around April 29, 1998, Purepac notified Warner-Lambert (prior to its purchase by Pfizer), that Purepac had filed its ANDA, and that it would not seek to market its generic gabapentin anhydrous for the treatment of epilepsy until the expiration of the '544 patent on January 16, 2000.

51. On or around June 14, 1998, Warner-Lambert commenced a patent infringement litigation in the United States District Court for the District of New Jersey, alleging infringement of the '476 and '479 patents. On or around July 17, 1998, Purepac filed its Answer and Counterclaim, alleging that both the '476 and '479 patents were invalid and unenforceable, and that Purepac's prospective generic did not infringe them. Purepac also stated a counterclaim for unfair competition under New Jersey law, alleging that Pfizer listed the '476 and '479 patents knowing that they did not cover the use of gabapentin anhydrous in the treatment of epilepsy, and solely for the purpose of forestalling generic competition for Neurontin.

52. On or about September 3, 1999, Purepac filed ANDA No. 75-694 seeking approval to market generic gabapentin anhydrous 600 and 800 mg. tablets after the expiration of the '544 patent on January 16, 2000. As with the capsules, Purepac sought to market gabapentin anhydrous tablets as "adjunctive therapy in the

treatment of partial seizures with and without secondary generalization in adults with epilepsy".

53. In ANDA No. 75-694, Purepac made a paragraph III certification regarding the '544 patent, and paragraph IV certifications as to the '476 and '479 patents. In December 1999, Warner-Lambert filed another suit against Purepac, this one alleging that Purepac's ANDA No. 75-694 would infringe the '476 and '479 patents.

54. On April 25, 2000, about three months after the expiration of the '544 patent, Pfizer procured the listing of the '482 patent in the Orange Book under both Neurontin tablets and capsules. On June 15, 2000, Purepac amended both of its ANDAs to add paragraph IV certifications that its ANDAs did not infringe the '482 patent. On July 15, 2000, Pfizer (which had just purchased Warner-Lambert) filed yet another suit in the New Jersey District Court, claiming that Purepac's ANDAs infringed the '482 patent and starting a new 30-month stay.

55. Purepac's answer to this second suit included a counterclaim for violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. On December 22, 2000, Pfizer's motion to dismiss the antitrust claim was denied.

2. Apotex

56. On April 17, 1998, Apotex Corp., a wholly-owned subsidiary of Apotex, Inc., and TorPharm, Inc., another wholly-

owned subsidiary of Apotex, Inc. (collectively referred to herein as "Apotex"), filed ANDA No. 75-360 seeking approval to market 100, 300, and 400 mg. gabapentin anhydrous capsules as "adjunctive therapy in the treatment of partial seizures with and without secondary generalization in adults with epilepsy". Like Purepac, Apotex filed a Paragraph III certification as to the '544 patent, but unlike Purepac, Apotex filed Paragraph IV certifications as to both the '476 and '479 patents.

57. On July 14, 1998, Warner-Lambert filed a patent infringement litigation against Apotex in the United States District Court for the District of Illinois, claiming that Apotex's ANDA would infringe the '476 and '479 patents. Apotex answered on August 14, 1998, alleging that neither patent would be infringed and that the '479 patent was invalid.

58. In or around May 2000, shortly after the issuance of the '482 patent on April 25, 2000 and its concurrent listing in the Orange Book, Apotex certified that its ANDA No. 75-360 would not infringe the '482 patent. On July 20, 2000, Pfizer filed an additional suit against Apotex in the Northern District of Illinois for infringement of the '482 patent, which triggered a new 30-month stay.

59. In November 2000, Apotex asserted counter-claims for violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, alleging that Warner-Lambert had submitted false and fraudulent

information to the FDA in order to obtain the listing of the '476 and '479 patents in the Orange Book, thus enabling Warner-Lambert to abuse Hatch-Waxman to extend its patent monopoly past January 16, 2000, the date of the expiration of the last patent claiming the use of gabapentin anhydrous for the treatment of epilepsy.

60. On March 2, 2001, the Illinois District Court granted Apotex summary judgment of non-infringement of the '476 patent "[b]ecause plaintiff has not responded to defendants' motion for summary judgment with facts sufficient to prevent the entry of summary judgment, and because plaintiff agrees that summary judgment is appropriate."

61. On September 13, 2001, the Illinois District Court granted Apotex summary judgment of non-infringement of the '479 patent, holding that "[t]here is no genuine issue of material fact on plaintiff's claim that defendant's proposed gabapentin product will infringe the '479 patent. Accordingly, defendants are entitled to judgment as a matter of law."

62. On or around June 15, 2000, Apotex amended its ANDA to include a paragraph IV certification that its ANDA did not infringe the '482 patent. On July 20, 2000, Pfizer filed another suit in the Illinois District Court, alleging that Apotex's ANDA infringed the '482 patent.

3. Other ANDA Filers

63. Pfizer has filed similar litigations, alleging that the ANDAs of other generic manufacturers, including Geneva Pharmaceuticals, Inc.; Teva Pharmaceuticals USA; Zenith Goldline Pharmaceuticals; and Eon Labs Manufacturing, infringe the '476, '479, and '482 patents. Several of these generic manufacturer defendants have filed counterclaims alleging the Pfizer's conduct constitutes a violation of section 2 of the Sherman Act, 15 U.S.C. § 2.

4. Pfizer's Litigation Conduct is Not Immune

64. The Noerr-Pennington doctrine does not immunize Pfizer's illegal conduct from antitrust liability, because the patent litigation actions brought by Pfizer were "shams", which no litigant could reasonably have expected to win, and which were prosecuted solely for the purpose of delaying entry of generic competition to the market for gabapentin anhydrous.

E. Pfizer's Wrongdoing

65. Pfizer knew that it had deceived the FDA when it listed its '476, '479, and '482 patents in the Orange Book as covering Neurontin, because it knew that none of those patents claimed the approved NDA drug, gabapentin anhydrous, nor its only approved use, treatment of epilepsy. Pfizer also knew that the patent on the use of gabapentin anhydrous in the treatment of epilepsy expired on January 16, 2000, and that the '476, '479, and '482

patents would not be infringed by the sale of generic gabapentin anhydrous solely for the treatment of epilepsy. Nevertheless, Pfizer prosecuted and continues to prosecute the patent litigations vigorously, because by doing so, it is able to forestall generic competition.

66. The specific intent and effect of Pfizer's multiple infringement lawsuits was to prevent generic manufacturers from marketing generic gabapentin anhydrous for the treatment of epilepsy in competition with Neurontin for as long as possible, by taking advantage of Hatch-Waxman.

VI. EFFECT ON INTERSTATE COMMERCE

67. At all material times, Neurontin, manufactured and sold by Pfizer, was shipped across state lines and sold to customers located outside its state of manufacture.

68. During the relevant time period, in connection with the purchase and sale of Neurontin, monies as well as contracts, bills and other forms of business communication and transactions were transmitted in a continuous and uninterrupted flow across state lines.

69. During the relevant time period, various devices were used to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign telephone commerce. The activities of Defendant, as

charged in this Complaint were within the flow of, and have substantially affected, interstate commerce.

VII. RELEVANT MARKETS

70. The relevant product market is the sale of gabapentin anhydrous -- i.e., Neurontin, and generic versions of Neurontin. There are no reasonably interchangeable anti-convulsant products without serious side effects that are available to prescribing physicians for the indications for which Neurontin is prescribed. A significant non-transitory price increase by Pfizer of its Neurontin product would not cause a significant loss of sales to other products.

71. The relevant geographic market is the United States and its territories.

72. Pfizer's market share in the relevant market is and has been at all relevant times 100%.

73. Pfizer's actions as part of, and in furtherance of, the illegal monopolization alleged herein, were authorized, ordered or done by Pfizer's officers, agents, employees or representatives while actively engaged in the management of Pfizer's affairs.

74. Pfizer's illegal acts to prevent the introduction into the U.S. marketplace of any generic version of Neurontin resulted in Plaintiff and the Class paying more than they would have paid for gabapentin anhydrous, absent Pfizer's illegal conduct.

VIII. EFFECTS ON COMPETITION

75. Pfizer's exclusionary conduct has prevented generic entry into the relevant market, and unlawfully enabled Pfizer to sell Neurontin without being subject to generic competition. But for Pfizer's illegal conduct, generic competitors would have begun marketing generic versions of Neurontin by at least January 16, 2000, and additional generic competitors would have entered the market thereafter.

76. If generic competitors had been able to enter the market and compete with Pfizer, Plaintiff and other direct purchaser members of the Class would have substituted lower-priced generics for the higher-priced brand-name drug for some or all of their gabapentin anhydrous requirements, and would have received discounts on some or all of their Neurontin purchases.

IX. DAMAGES TO PLAINTIFF AND THE MEMBERS OF THE CLASS

77. During the relevant period, Plaintiff and the members of the Class purchased substantial amounts of Neurontin directly from Pfizer. As a result of Pfizer's illegal conduct, Plaintiff and the members of the Class were compelled to pay, and did pay, artificially inflated prices for their gabapentin anhydrous requirements. Those prices were substantially greater than the prices that members of the Class would have paid absent the illegal conduct alleged herein, because: (1) the price of branded Neurontin was artificially inflated by Pfizer's illegal conduct;

and/or (2) class members were deprived of the opportunity to purchase lower-priced generic gabapentin anhydrous instead of expensive brand-name Neurontin. As a consequence, Plaintiff and the members of the Class have sustained substantial losses and damage to their business and property in the form, among other things, of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial.

X. VIOLATIONS ALLEGED

COUNT I

Monopolization (15 U.S.C. § 2)

78. Plaintiff incorporates by reference the allegations above, as if fully set forth herein.

79. At all relevant times Pfizer possessed monopoly power over the relevant market - gabapentin anhydrous, i.e. Neurontin and generic versions of Neurontin - in the United States. But for Pfizer's exclusionary and anti-competitive conduct, as alleged herein, Pfizer would not have been able to maintain its monopoly power over the relevant market.

80. Pfizer wrongfully maintained its monopoly power by, *inter alia*: (a) knowingly and willfully making false and misleading representations to the FDA to obtain the listing of its '476, '479, and 482 patents in the FDA's Orange Book; and

(b) prosecuting baseless, sham patent litigation against its prospective generic competitors.

81. Pfizer's acts were taken in bad faith, for the purpose and with the effect of maintaining its monopoly in the relevant market.

82. Plaintiff has been injured in its business and property by reason of Pfizer's anti-competitive activities. Plaintiff's injury consists of paying higher prices for gabapentin anhydrous than it would have in the absence of Pfizer's anti-competitive conduct. Plaintiff's injury is of the type the antitrust laws were designed to prevent and flows from that which makes Defendant's conduct unlawful.

X. DEMAND FOR JURY

141. Plaintiff demands trial by jury on all issues so triable.

XI. PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of itself and the Class, respectfully prays that:

- (i) The Court determine that this action may be maintained as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure, and direct that reasonable notice of this action, as provided by Rule 23(c)(2) of the Federal Rules of Procedure, be given to the Class;
- (ii) The acts alleged herein be adjudged and decreed to be an unlawful restraint of trade in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2;

- (iii) Each member of the Class recover three-fold the damages determined to have been sustained by each of them, and that joint and several judgment be entered against each Defendant in favor of the Class;
- (iv) The Class recover their costs of suit, including reasonable attorneys' fees as provided by law; and

(v) The Class be granted such other, further relief as the nature of the case may require or as may be determined to be just, equitable, and proper by this Court.

Dated: April 18, 2002

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